

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

In re Lamictal Direct Purchaser
Antitrust Litigation

Master File No. 2:12-cv-995-WHW-
CLW

ORAL ARGUMENT REQUESTED

This Document Relates to All Actions

(Filed Provisionally Under Seal)

**MEMORANDUM OF LAW IN OPPOSITION
TO PLAINTIFFS' MOTION FOR CLASS CERTIFICATION**

Jay P. Lefkowitz, P.C.
Devora W. Allon
Dmitriy Tishyevich
Thomas S. Burnett
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
(212) 446-4800

Michael E. Patunas
PATUNAS LAW LLC
24 Commerce Street, Suite 606
Newark, NJ 07102
(973) 396-8740

*Attorneys for Teva Industries Ltd. and
Teva Pharmaceuticals USA, Inc.*

Robin Sumner
Daniel Boland
Lindsay Breedlove
PEPPER HAMILTON LLP
3000 Two Logan Square
Eighteenth & Arch Streets
Philadelphia, PA 19103-2799
(215) 981-4000

Gavin Rooney
Joseph Fischetti
LOWENSTEIN SANDLER LLP
One Lowenstein Drive
Roseland, NJ 07068
(973) 597-2500

Attorneys for GlaxoSmithKline LLC

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION.....	1
FACTUAL BACKGROUND.....	3
A. Brand and generic manufacturers sell to different direct purchasers and set customer-specific prices.....	3
B. GSK and Teva settled a patent lawsuit over the brand drug Lamictal.....	4
C. [REDACTED].....	5
D. [REDACTED].....	6
E. Plaintiffs sued GSK and Teva on behalf of a class that has two groups of purchasers with different theories of injury and damages.	8
1. <u>Plaintiffs try to show brand-generic injury and damages by relying on a penetration rate that includes generic-only purchasers.</u>	9
2. <u>Plaintiffs try to show generic injury by relying on average prices and ignoring [REDACTED]</u>	10
ARGUMENT.....	11
I. Plaintiffs Face a Heavy Burden in Certifying a Class and Cannot Rely on Averages that Mask Differences Between Purchasers.	12
II. Plaintiffs Violate the Rules Enabling Act and Cannot Prove Predominance Because Their Average Penetration Rate Inflates Damages and Hides Uninjured Purchasers.....	14
A. The penetration rate does not fit the theory of liability and inflates damages.....	14
B. The penetration rate hides uninjured brand purchasers.	18
III. Plaintiffs Cannot Prove Predominance Because Common Evidence About Average Prices Does Not Show Generic Purchasers Were Injured.	20
A. Evidence of average price changes cannot show generic-purchaser injury because it fails to account for [REDACTED].	20
B. Plaintiffs’ sensitivity analysis does not prove classwide injury.....	23

TABLE OF CONTENTS (CONT'D)

	<u>Page</u>
C. Plaintiffs cannot prove classwide generic-purchaser injury even if GSK would have launched an authorized generic <i>and</i> pursued [REDACTED] [REDACTED].	24
D. At most, this Court can certify a class only on the dual-strategy theory.	26
IV. Plaintiffs Cannot Prove that Joinder is Impracticable or that a Class is Superior.	27
CONCLUSION	30

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Abu Dhabi Commercial Bank v. Morgan Stanley & Co.</i> , 269 F.R.D. 252 (S.D.N.Y. 2010)	29
<i>In re Androgel Antitrust Litig.</i> , 2018 WL 3424612 (N.D. Ga. July 16, 2018).....	28
<i>In re Chocolate Confectionary Antitrust Litig.</i> , 289 F.R.D. 200 (M.D. Pa. 2012).....	19
<i>Comcast Corp. v. Behrend</i> , 569 U.S. 27 (2013).....	<i>passim</i>
<i>Copperweld Corp. v. Indep. Tube Corp.</i> , 467 U.S. 752 (1984).....	29
<i>Dzielak v. Whirlpool Corp.</i> , 2017 WL 6513347 (D.N.J. Dec. 20, 2017).....	17, 27
<i>Gates v. Rohme & Haas Co.</i> , 655 F.3d 255 (3d Cir. 2011).....	13, 19
<i>In re Hydrogen Peroxide Antitrust Litig.</i> , 552 F.3d 305 (3d Cir. 2008).....	13, 20, 26
<i>In re K-Dur Antitrust Litig.</i> , 686 F.3d 197 (3d Cir. 2012).....	19
<i>King Drug Co. v. Cephalon, Inc.</i> , 2017 WL 3705715 (E.D. Pa. Aug. 28, 2017)	28, 29, 30
<i>Lewis v. Anderson</i> , 477 A.2d 1040 (Del. 1984)	28
<i>Lewis v. Casey</i> , 518 U.S. 343 (1996).....	19
<i>In re Linerboard Antitrust Litig.</i> , 223 F.R.D. 357 (E.D. Pa. 2004).....	29
<i>Marcus v. BMW of N. Am. LLC</i> , 687 F.3d 583 (3d Cir. 2012).....	12, 27, 28

TABLE OF AUTHORITIES (CONT'D)

	<u>Page(s)</u>
<i>McLaughlin v. Am. Tobacco Co.</i> , 522 F.3d 215 (2d Cir. 2008).....	15, 17
<i>In re Modafinil Antitrust Litig.</i> , 837 F.3d 238 (3d Cir. 2016).....	<i>passim</i>
<i>Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.</i> , 259 F.3d 154 (3d Cir. 2001).....	27
<i>In re Park Cent. Glob. Litig.</i> , 2014 WL 4261950 (N.D. Tex. Aug. 25, 2014).....	29
<i>In re Pharmacy Benefit Mgrs. Antitrust Litig.</i> , 2017 WL 275398 (E.D. Pa. Jan. 18, 2017).....	16
<i>In re Plastics Additives</i> , 2010 WL 3431837 (E.D. Pa. Aug. 31, 2010)	22
<i>In re Processed Egg Prods. Antitrust Litig.</i> , 312 F.R.D. 124 (E.D. Pa. 2015).....	13, 15, 19, 21
<i>Sanneman v. Chrysler Corp.</i> , 191 F.R.D. 441 (E.D. Pa. 2000).....	28, 30
<i>Seijas v. Rep. of Arg.</i> , 606 F.3d 53 (2d Cir. 2010).....	15
<i>Teva Pharm. Indus. v. SmithKline Beecham Corp.</i> , 2009 WL 1687457 (D.N.J. June 16, 2009).....	6
<i>Tyson Foods, Inc. v. Bouaphakeo</i> , 136 S. Ct. 1036 (2016).....	13, 15, 18, 19
<i>Vista Healthplan, Inc. v. Cephalon, Inc.</i> , 2015 WL 3623005 (E.D. Pa. June 10, 2015)	21
Statutes	
28 U.S.C. §2072(b)	15
Rules	
Fed. R. Civ. P. 23.....	<i>passim</i>

INTRODUCTION

This is not the run-of-the-mill proposed class action that Plaintiffs make it out to be. For the first time in this Circuit, Plaintiffs seek to represent two groups of companies—with two different theories of liability—in the same class. One group bought brand Lamictal directly from GSK. They allegedly suffered harm because they would have switched from brand Lamictal to generic lamotrigine if the generic had become available earlier. This switching theory of liability is common in this type of litigation, but presents a numerosity problem here: at most, only 32 purchasers bought Lamictal directly from GSK, well short of the number typically required.

Plaintiffs' solution is to claim that purchasers who bought generic lamotrigine *also* were harmed—not because they would have switched from brand to generic, but because they would have paid a lower price for the generic if GSK had launched an authorized generic. This generic-purchaser theory of liability expands the size of the proposed class by sweeping in a second group of companies that bought generic lamotrigine directly from Teva but, unlike other members of the proposed class, *never* bought brand Lamictal from GSK. Including these companies inflates the class to 65 direct purchasers, rather than just 32.

In order to make these two distinct theories of liability appear susceptible to classwide treatment, Plaintiffs rely on classwide averages in a way that inflates aggregate damages and ignores critical differences between brand purchasers and generic purchasers. This creates several Rule 23 problems that warrant denial of Plaintiffs' motion.

First, for brand purchasers, Plaintiffs use classwide averages to inflate aggregate damages and hide uninjured class members. In theory, these buyers were harmed because they would have switched some of their Lamictal purchases to lamotrigine. But rather than use evidence of brand purchasers switching, Plaintiffs calculate damages based on the average rate at which the *entire class* bought lamotrigine—including generic-only purchasers that didn't switch at all. That

methodology is inconsistent with the switching theory of liability and overstates the amount of lamotrigine that brand purchasers would have bought, inflating aggregate damages by over [REDACTED]—a problem that cannot be fixed when apportioning damages. Plaintiffs’ use of averages also hides the fact that not all of these brand purchasers switched to lamotrigine when Teva began selling the generic. These problems prevent class certification: they defeat predominance because properly evaluating injury and damages requires an individualized assessment of switching, and they violate the Rules Enabling Act by using the class action as a tool to inflate aggregate damages.

Second, for generic purchasers, Plaintiffs ignore customer-specific complexities that make it impossible to prove injury on a classwide basis. Their simplistic theory is that, just like a generic is on average cheaper than a brand, generic prices would be lower on average in a but-for world with two generics (one of which supposedly would have been GSK’s authorized generic) than they were in the actual world with only one. But the reality of lamotrigine pricing is more complex.

[REDACTED] Importantly, though, [REDACTED]

[REDACTED] Proving that generic purchasers were injured, then, does not turn simply on whether lamotrigine would have been cheaper with two versions on the market. Instead, Plaintiffs have to show that generic purchasers would have received better prices [REDACTED]

[REDACTED] Because generic purchasers paid different amounts, that comparison requires individualized analysis that defeats predominance.

These unique problems stem from Plaintiffs’ attempt to cobble together a class where one should not exist. The putative class members are sizable companies, [REDACTED] stand to win over [REDACTED]. In these circumstances, the usual class of brand purchasers would not justify

certification with only 32 members. But adding a generic-purchaser theory of liability to rope in more class members does not solve the problem. For one, the only way to fix the issues that Plaintiffs' approach creates would be to drop the generic-purchaser theory of relief—shrinking the class size back down to only 32 brand purchasers. And more fundamentally, class actions are not a mechanism for patching together groups of capable litigants to inflate damages and hide uninjured members. This Court should refuse to certify Plaintiffs' inventive new class.

FACTUAL BACKGROUND¹

A. Brand and generic manufacturers sell to different direct purchasers and set customer-specific prices.

The path a drug takes to get from manufacturer to consumer depends on whether the drug is a brand or a generic. Brand manufacturers typically begin by selling their products to a wholesaler. Ex. 1 to Burnett Decl. (“Ex.”), Hughes Rpt. ¶26 (“Hughes”). The wholesaler then resells the brand drug to a pharmacy, where the consumer can buy it. *Id.* That means that when only a brand version of a drug is available, “direct purchasers”—those that buy from the manufacturer, rather than an intermediary—consist primarily of wholesalers.

Generic drugs have a different distribution system. A generic manufacturer will sell some of its product through the same channel that the brand drug travels: from wholesaler, to pharmacy, to consumer. *Id.* But the generic manufacturer will sell the rest directly to pharmacies, cutting out the wholesaler as a middleman. *Id.* So when a generic becomes available, the set of “direct purchasers” expands from wholesalers alone to include pharmacies. The former buy brand *and* generic products directly from the manufacturer, while the latter buy only generics directly.

The price each direct purchaser pays for the brand or generic varies. [REDACTED]

¹ Defendants disagree with much of Plaintiffs' description of the facts but, because those disagreements are not relevant to class certification, will not address them in this brief. Br. 7-16.

manufacturers negotiate customer-specific prices, so two companies buying the same drug directly from the same manufacturer often pay different prices. *Id.* ¶¶23-29. Even wholesalers, which theoretically pay a uniform “wholesale acquisition cost,” end up paying different amounts for the same products due to wholesaler-specific rebates, discounts, and chargebacks. *Id.*

B. GSK and Teva settled a patent lawsuit over the brand drug Lamictal.

In 1994, GSK began selling Lamictal, a brand drug used to treat epilepsy and bipolar disorder. Ex. 2, Stangle Rpt. ¶3 (“Stangle”). The drug comes in four strengths, each with a different price. *Id.* Like many brand manufacturers, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Teva developed lamotrigine, a generic version of Lamictal, and in 2002 informed GSK that it did not believe the generic infringed any valid patents. Stangle ¶8. The notice triggered a statutory process for litigating patent disputes and entitled Teva to 180 days as the sole generic manufacturer (aside from a potential authorized generic) if it won or settled that litigation. *Id.* ¶7.

When Teva sent its notice to GSK, GSK’s patent on Lamictal was set to run until July 2008, with a possible extension until January 2009. *Id.* ¶¶4-6. GSK filed an infringement suit, which the parties took to trial. [REDACTED]—weeks before any ruling on the merits—and concluded with a settlement agreement in early 2005. *Id.* ¶¶9-10; Ex. 3 (Interrog. No. 15). Under the settlement, GSK gave Teva the right to launch a chewable version of lamotrigine in June 2005 and lamotrigine tablets on July 22, 2008. Stangle ¶10. GSK’s extended patents were not set to expire until six months later, and GSK promised it would not launch an authorized generic version of lamotrigine until then, making Teva the sole lamotrigine tablet provider from July 22, 2008 until January 22, 2009 (the “Teva exclusivity period”). *Id.*

C. [REDACTED]

Despite the apparent concession, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

GSK began to build a strategy around this theory, and [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] in a market with an authorized generic, “the brand-name product captures a smaller share of revenues” than when there is only one generic—a process known as “cannibalization.” Ex. 7, at 59 (2011 FTC Rpt.). [REDACTED]

[REDACTED]

[REDACTED]

² Contrary to Plaintiffs’ suggestion, [REDACTED]

[REDACTED]

[illegible][illegible]

D. [REDACTED]

As Teva prepared to launch lamotrigine in 2008, [REDACTED]

Teva had two responses. First, it sued GSK, arguing that the Strategy violated the settlement agreement. A court dismissed the suit, finding that “competition between Teva’s generic and Lamictal is precisely what the [settlement] envisioned.”³

³ *Teva Pharm. Indus. v. SmithKline Beecham Corp.*, 2009 WL 1687457, *4 (D.N.J. June 16, 2009).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

4 [REDACTED]

After launching, Teva was the sole lamotrigine manufacturer from July 22, 2008 through January 22, 2009. It sold directly to a mix of wholesalers, pharmacies, and other entities. Of the 32 companies that had bought Lamictal from GSK before generic entry, 27 bought lamotrigine from Teva during the exclusivity period. *Id.* Supp. Ex. 2. In addition, 33 companies that did *not* buy Lamictal from GSK—primarily pharmacies—bought lamotrigine from Teva. *Id.* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

On January 22, 2008, Teva’s exclusivity period ended. Five days later, eight other generic lamotrigine manufacturers entered the market. Stangle ¶13.

E. Plaintiffs sued GSK and Teva on behalf of a class that has two groups of purchasers with different theories of injury and damages.

Plaintiffs filed suit, claiming that the settlement agreement between GSK and Teva violated federal antitrust law. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Plaintiffs seek to represent a class of companies that bought Lamictal or lamotrigine directly. Although they say the class has 65 members, they gloss over a key distinction—not all 65 bought Lamictal from GSK. Only 32 bought Lamictal from GSK (brand purchasers). The other 33 only bought lamotrigine directly (generic-only purchasers). Hughes Ex. 2. To bring both groups into the fold, Plaintiffs need to pursue two distinct theories of injury and damages.

1. Plaintiffs try to show brand-generic injury and damages by relying on a penetration rate that includes generic-only purchasers.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

To translate this switching theory of injury into [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Each step of these calculations uses averages.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Plaintiffs try to show generic injury by relying on average prices and ignoring the [REDACTED]

Plaintiffs have a different theory of injury and damages for generic purchasers. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

ARGUMENT

Plaintiffs cannot carry their burden to certify this unique Rule 23(b)(3) class. A class of brand purchasers would have only 32 members, failing the numerosity requirement. *See In re Modafinil Antitrust Litig.*, 837 F.3d 238, 249 (3d Cir. 2016). By trying to expand the class to include generic-only purchasers through their generic-purchaser theory of liability, Plaintiffs have just created additional Rule 23 problems. With respect to brand purchasers, using a classwide average penetration rate that includes generic-only buyers is inconsistent with the switching theory of liability, inflates damages by over [REDACTED] and hides uninjured purchasers. These problems defeat predominance and mean certification would violate the Rules Enabling Act.

The generic-purchaser theory of liability presents a separate set of complexities. [REDACTED]

[REDACTED]

[REDACTED] even though the key issue for proving injury to generic purchasers in this case is whether they paid a higher price in the actual world than they would have in a but-for world [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Plaintiffs’ classwide evidence about how average prices change with multiple generics on the market is irrelevant: it does not [REDACTED] and masks customer-specific price differences. The need for an individualized inquiry defeats predominance.

Finally, joinder would be practical and preferable to a class action. Plaintiffs’ attempt to increase the class size doesn’t work. Separating the generic-purchaser theory of liability is the only way to even begin fixing any of the Rule 23 problems Plaintiffs have created, but that would leave a class of 32 brand purchasers pursuing a switching theory of liability. That is too small for certification. Indeed, even a class of 65 purchasers would not warrant certification. The plaintiffs are large companies, nearly all of which could win a substantial amount of money, and the many individualized issues mean that a class is not more manageable than litigating through joinder.

I. Plaintiffs Face a Heavy Burden in Certifying a Class and Cannot Rely on Averages that Mask Differences Between Purchasers.

“The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only.” *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013). “To come within the exception, a party seeking to maintain a class action must affirmatively demonstrate [its] compliance with Rule 23.” *Id.* This is no mere pleading rule. “The party seeking certification bears the burden of establishing each element of Rule 23 by a preponderance of the evidence,” and “a district court must conduct a rigorous analysis” to “resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits.” *Marcus v. BMW of N. Am. LLC*, 687 F.3d 583, 591 (3d Cir. 2012). “This point is especially important . . . when a party opposing certification offers expert opinion” because weighing “conflicting expert testimony at the certification stage is not only permissible; it may be integral to the rigorous analysis Rule 23

demands.” *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323 (3d Cir. 2008).

Class actions under Rule 23(b)(3), like the one here, require particularly tough scrutiny. This “adventuresome innovation” is “designed for situations” where a class action “is not clearly called for.” *Comcast*, 569 U.S. at 34. To justify the class, Plaintiffs must prove that (1) “questions of law or fact common to class members predominate over any questions affecting only individual members”; and (2) “a class action is superior to other available methods”. Fed. R. Civ. P. 23(b)(3).

This analysis demands that courts take a “close look” at plaintiffs’ proof, which requires vigilance about the possible misuse of averages. *Comcast*, 569 U.S. at 34. Averages may be a “permissible method of proving classwide liability” if “each class member could have relied on that [average] to establish liability if he or she had brought an individual action.” *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016). But that won’t always be the case. Averages can paint a misleading picture of the facts by masking wide variation between different class members. *See, e.g., Gates v. Rohme & Haas Co.*, 655 F.3d 255, 266-67 (3d Cir. 2011) (finding “any one class member may have an exposure level well above or below the average”); *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 124, 159-61 (E.D. Pa. 2015) (rejecting model that used averages to “mask[] individualized issues”). And if not scrutinized, they can “violate[] the Rules Enabling Act” by “giving plaintiffs” a different option for proving their claim “than they could have asserted in an individual action.” *Tyson*, 136 S. Ct. at 1048. As a result, attempts to meet the Rule 23 requirements by using averages that “do not reflect the individual characteristics of class members have been met with skepticism.” *Gates*, 655 F.3d at 266.

Here, by using averages, Plaintiffs measure brand-generic damages in a way that does not match their switching theory of liability and inflates aggregate damages. They also hide uninjured brand and generic purchasers. These problems are sufficient to defeat class certification.

II. Plaintiffs Violate the Rules Enabling Act and Cannot Prove Predominance Because Their Average Penetration Rate Inflates Damages and Hides Uninjured Purchasers.

Plaintiffs say that companies that bought Lamictal directly from GSK would have switched some of their purchases to lamotrigine if it had hit the market earlier. To prove injury and damages, they rely on Dr. Lamb’s average classwide generic penetration rate. But Dr. Lamb’s calculation of that rate does not focus only on purchases by companies that bought Lamictal; it also includes *generic-only* purchasers. That leads to two fatal problems: first, it creates a mismatch between the switching theory of liability and Plaintiffs’ damages methodology, which results in artificially inflating the penetration rate and overstating aggregate damages. And second, it hides the fact that some brand purchasers *did not* switch to lamotrigine and thus have no injury in the first place.

A. The penetration rate does not fit the theory of liability and inflates damages.

Plaintiffs calculate brand-purchaser damages by relying on the amount of lamotrigine that *all* direct purchasers bought, not just brand purchasers. That methodology defeats predominance and makes certification impossible without violating the Rules Enabling Act because it does not fit Plaintiffs’ theory of liability and uses the class-action mechanism to artificially inflate damages.

Plaintiffs can seek aggregate damages only if they satisfy two prerequisites. First, the “model purporting to serve as evidence of damages . . . must measure only those damages attributable” to the plaintiff’s theory of liability. *Comcast*, 569 U.S. at 35. “If the model does not even attempt to do that, it cannot possibly establish that damages are susceptible of measurement across the entire class”—a critical aspect of proving predominance. *Id.* In *Comcast*, for instance, plaintiffs’ damages model assumed that they would prevail on four theories of antitrust injury, even though the court had dismissed all but one. *Id.* at 36-37. The Supreme Court found that common issues did not predominate because the damages study did not translate plaintiffs’ “*legal theory of the harmful event* into an analysis of the economic impact of *that event*.” *Id.*

Second, the method for proving aggregate damages cannot inflate the figure significantly beyond what class members would receive if they litigated individually. The Rules Enabling Act prevents plaintiffs from using class actions to “abridge, enlarge, or modify any substantive right.” 28 U.S.C. §2072(b); *Tyson Foods*, 136 S. Ct. at 1046. As applied to damages in particular, that means plaintiffs can’t take advantage of litigating as a class to invent a theory of damages that inflates the liability the defendant faces. *See Seijas v. Rep. of Arg.*, 606 F.3d 53, 58-59 (2d Cir. 2010) (finding aggregate damages “enlarge[] plaintiffs’ rights” and violate Rules Enabling Act when they do not “reflect the aggregate amount owed to class members”); *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 231-32 (2d Cir. 2008) (holding aggregate “damages. . . that bear[] little or no relationship to the amount of economic harm” violate Rules Enabling Act); *see Processed Egg*, 312 F.R.D. at 161 (requiring “reliable means for measuring damages . . . in the aggregate”). “[A]ggregate calculations that result in inflated damages figures . . . violate[] the Rules Enabling Act.” 4 Newberg on Class Actions §12:2 (5th ed. 2018).

Plaintiffs cannot meet either requirement. Like in *Comcast*, there is a fundamental mismatch between Plaintiffs’ switching theory of liability and their method for calculating damages. [REDACTED]

[REDACTED] That should lead to an equally simple method of calculating damages: Plaintiffs could calculate the penetration rate by looking at the extent to which those *brand purchasers* switched from Lamictal to lamotrigine once it became available in the actual world, then use that as a proxy for switching in the but-for world. So, for example, if half of a company’s direct purchases were lamotrigine in the first month after generic entry, Plaintiffs could argue that company would have bought the same mix if generic entry happened earlier.

But that is not how Plaintiffs attempt to calculate brand-generic damages. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Plaintiffs thus calculate the extent to which the *entire direct purchaser market* bought lamotrigine, not the extent to which *brand purchasers* switched from the brand to the generic. Trouble is, their theory of liability for brand purchasers is based only on how brand purchasers would have switched to lamotrigine. *See Hughes* ¶61. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Yet in attempting to calculate brand-generic damages, he used a penetration rate based on the amount of lamotrigine that *all* direct purchasers bought. This is the same failure to translate the “*legal theory of the harmful event*” into an analysis of the economic impact *of that event*” that *Comcast* prohibited. 569 U.S. at 38; *see In re Pharmacy Benefit Mgrs. Antitrust Litig.*, 2017 WL 275398, at *19-20 (E.D. Pa. Jan. 18, 2017) (rejecting class when “theory of antitrust impact” did not “match the damages model”).

⁵ [REDACTED]

This mismatch also means certification would violate the Rules Enabling Act because, by including generic-only purchasers in the penetration rate, Plaintiffs dramatically inflate *aggregate* damages. *See Dzielak v. Whirlpool Corp.*, 2017 WL 6513347, at *12 (D.N.J. Dec. 20, 2017) (finding evidence that “could not be used if one of the class members brought an individual action” violates the Rules Enabling Act). After generic entry, many brand purchasers continued to buy a healthy chunk of Lamictal. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This is not a mere “difference among the [class] members” that raises issues about how to *divide* damages. Br. 36-38 & n.118. By bringing generic-only purchasers into the class, Plaintiffs have increased the damages from their switching theory and, as a result, inflated *aggregate* damages for the class. Certifying the class would violate the Rules Enabling Act because the class action mechanism would increase the total amount Plaintiffs stand to recover, running up GSK and Teva’s exposure. *See McLaughlin*, 522 F.3d at 231. If Plaintiffs want aggregate damages, they have to follow the rules: the damages they claim must fit the theory of liability, and the class action cannot be used as a tool to invent damages that would not be available to class members if

they litigated individually. Because Plaintiffs break both rules, the class cannot be certified.

B. The penetration rate hides uninjured brand purchasers.

There is another problem with Plaintiffs' average generic penetration rate: it conceals that some brand purchasers did not switch to lamotrigine when it launched and thus suffered no injury.

Rule 23(b)(3) requires Plaintiffs to prove that common issues predominate over individual ones. Evaluating that proof demands "careful scrutiny to the relation between common and individual questions in a case." *Tyson Foods*, 136 S. Ct. at 1045. "An individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized class-wide proof." *Id.*

[REDACTED]

This is wrong because not all brand purchasers [REDACTED] By focusing on marketwide trends, Dr. Lamb ignores that a number of brand purchasers did not switch to buying generics *at all* during the relevant time period. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The upshot is that deciding whether brand purchasers were injured requires evidence that “varies from member to member.” *Tyson Foods*, 136 S. Ct. at 1045. Dr. Lamb’s analysis does not prove brand purchasers would have switched to lamotrigine; instead, he relies on averages to sweep those who didn’t under the rug. Using averages to “mask[] individualized issues” does not satisfy Rule 23. *Processed Egg*, 312 F.R.D. at 159-60; *see Gates*, 655 F.3d at 266. To prove that these non-switching brand purchasers suffered an injury, Plaintiffs would have to go one-by-one.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] None of this is capable of proof using classwide evidence.

Plaintiffs counter that a class can include “uninjured members.” Br. 31. That does not solve the problem. For one, courts have no “power to presume and remediate harm that has not been established.” *Lewis v. Casey*, 518 U.S. 343, 357-58, 360 n.7 (1996). As a result, the cases Plaintiffs cite require a way to ensure uninjured plaintiffs do not recover, including by removing them from the class.⁶ At best, then, the non-switching purchasers should be excluded. But even that best-case option does not work. To satisfy predominance, the number of potentially uninjured class members must be de minimis. *K-Dur*, 686 F.3d at 222 (requiring “virtually all” members be

⁶ *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 220 & n.13 (3d Cir. 2012) (noting that “all of the class members purchased some of the generic”); *In re Chocolate Confectionary Antitrust Litig.*, 289 F.R.D. 200, 222 n.30 (M.D. Pa. 2012) (requiring that “unaffected customers . . . be removed”).

injured). Here, however, non-switching purchasers are over 15% of all brand purchasers in the class. As explained below, there is also an even larger number of uninjured generic purchasers. The need for individualized analysis of so many buyers defeats predominance.

III. Plaintiffs Cannot Prove Predominance Because Common Evidence About Average Prices Does Not Show Generic Purchasers Were Injured.

Plaintiffs have a different theory of liability for generic purchasers, which includes both (1) brand purchasers that bought generics and (2) generic-only purchasers. Plaintiffs say these companies were harmed on their lamotrigine purchases because, in the but-for world, Teva would have launched with competition from an authorized generic, leading to lower generic prices. The problem with this theory is that [REDACTED]

[REDACTED] Determining if any given generic purchaser was injured, then, does not turn on whether, as a general matter, generic prices tend to fall when two generics are on the market. Instead, it requires [REDACTED]

[REDACTED] That comparison must be done on a purchaser-by-purchaser basis, which is fatal to Plaintiffs' motion.

A. Evidence of average price changes cannot show generic-purchaser injury because it [REDACTED]

“In antitrust cases, impact often is critically important for the purpose of evaluating Rule 23(b)(3)’s predominance requirement because it is an element of the claim that may call for individual, as opposed to common, proof.” *Hydrogen Peroxide*, 552 F.3d at 311. The district court must conduct a “rigorous assessment of the available evidence and the method or methods by which plaintiffs propose to use the evidence to prove impact at trial.” *Id.* at 311-12. The standard does not “relax . . . merely because” plaintiffs have filed an antitrust claim. *Id.* at 322.

Failure to establish that proof of injury is capable on a classwide basis prevents common issues from predominating and defeats class certification. *E.g.*, *Processed Egg*, 312 F.R.D at 160-61; *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005, at *16-17 (E.D. Pa. June 10, 2015).

Here, Plaintiffs plan to prove injury to generic purchasers using evidence about average changes in generic prices when a second generic enters the market. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The problem with this evidence is that it does not address the key injury issue for generic buyers in this case. If assessing injury just required comparing a world with one generic to a world with two, Dr. Lamb's analysis might be useful. But it isn't that simple. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The problem is that this comparison requires going purchaser by purchaser. [REDACTED]

[REDACTED]

[REDACTED] Lamotrigine is no different. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

So proving generic-purchaser injury requires [REDACTED]

[REDACTED]

[REDACTED]

That analysis shows that many generic purchasers were not injured because they received

[REDACTED]

See In re Plastics Additives, 2010 WL 3431837, at *15-17 (E.D. Pa. Aug. 31, 2010) (rejecting class when data showed no impact for many members). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The FTC study cited in Dr. Lamb's report provides a useful reference point for this analysis. After evaluating hundreds of drugs, the FTC found that on average a second generic lowers prices by 7% to 14%.⁷ *Id.*; Ex. 7, at 48; Stangle ¶60. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁷ [REDACTED]

[REDACTED]

[REDACTED] Even if he had done this analysis, the problem for Plaintiffs would remain: the only way to assess generic-purchaser injury is mini-trials for each purchasers. That overwhelms other issues in the case, defeating predominance and the class more broadly.

B. Plaintiffs' [REDACTED] does not prove classwide injury.

Dr. Lamb tries to save the class [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] But his analysis does nothing of the sort; it just uses averages to cover up variation between purchasers.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This analysis cannot carry Plaintiffs' burden to prove that it is possible to establish generic injury on a classwide basis. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The result is that, when he compares his artificial average price to each generic-only purchaser's daily price, he has already eliminated all of the customer-specific variation that could show a purchaser would not have received a better lamotrigine price in the actual world than in a world [REDACTED]

[REDACTED] That is using averages to mask classwide differences, not to prove classwide injury.

C. Plaintiffs cannot prove classwide generic-purchaser injury even if GSK would

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] That is wrong and, in any event, would still require an individualized analysis to prove injury.

On the merits, there is no evidence that GSK [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Even if there were evidence that [REDACTED] that would still not help Plaintiffs prove injury on a classwide basis. In that scenario, the relevant question would be whether each generic purchaser that [REDACTED]

[REDACTED] None of Plaintiffs' evidence answers that question. [REDACTED]

[REDACTED]

[REDACTED] Nor do they address how prices might change in the unique scenario Plaintiffs imagine: [REDACTED]

[REDACTED]

Plaintiffs do not explain why, in that scenario, [REDACTED]

8

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Plaintiffs have no evidence about how prices would have changed in this competitive environment, much less evidence that *every* generic purchaser would pay a lower price than it actually did. That leaves them right back where they started: unable to prove generic-purchaser injury without individualized proof.

D. At most, this Court can certify a class only on the dual-strategy theory.

Because Dr. Lamb did not [REDACTED]

[REDACTED] Plaintiffs' only hope for proving classwide generic-purchaser injury is their theory that GSK [REDACTED] There is, once again, no support for that position. But if this Court decides Plaintiffs should nonetheless be allowed to pursue the theory, it should explicitly make proving the theory a precondition for obtaining relief.

Rule 23(b)(3) requires a "rigorous assessment of the . . . method or methods by which plaintiffs propose . . . to prove [antitrust] impact at trial." *Hydrogen Peroxide*, 552 F.3d at 312. If the Court decides that plaintiffs can prove classwide injury through one of those methods, its opinion "must include . . . a readily discernible, clear, and complete" description of the issues that can be resolved "on a class basis." *Id.* at 320-21. In light of that requirement, the Third Circuit and lower courts have looked closely at plaintiffs' theories of relief and certified only those that

are susceptible to classwide proof. *See Marcus*, 687 F.3d at 605-06 (distinguishing between theories of relief under same cause of action); *Dzielak*, 2017 WL 6513347, at *10 (same).

Under that rule, even if this Court were to conclude that Plaintiffs could establish generic-purchaser injury [REDACTED]

[REDACTED] this Court must require Plaintiffs to prove that point to obtain classwide relief. Without that proof, Plaintiffs would have no basis for recovering on their generic-purchaser theory of liability. And without that theory, their basis for a 65-member class would fall away.

IV. Plaintiffs Cannot Prove that Joinder is Impracticable or that a Class is Superior.

The proposed class is not a large group of people banding together to bring low-dollar claims. Rather, it is a cluster of corporations, the vast majority of which stand to win over [REDACTED] each. Litigating through joinder would be practicable and a class is not superior.

Plaintiffs have to pull double duty to justify the need for a class. First, Rule 23(a) requires them to prove that the “class is so numerous that joinder of all members is impracticable.” “This calls for an inherently fact-based analysis” based on “the context of the particular case.” *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 249 (3d Cir. 2016). “[D]istrict courts are always under an obligation to ensure that joinder is impracticable,” and the inquiry “should be particularly rigorous when the putative class consists of fewer than forty members.” *Id.* at 250. The key issues are whether a class is “substantially more efficient . . . than joinder,” and whether Plaintiffs have “the ability and motivation . . . to pursue their litigation via joinder.” *Id.* at 256-57.

Second, in a Rule 23(b)(3) class like this one, Plaintiffs must also prove that the “class action is superior to other available methods for . . . adjudicating the controversy.” That inquiry focuses on “the difficulties likely to be encountered in the management of a class action.” *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 191 (3d Cir. 2001). In particular, the presence of issues that need “individual litigation” can wipe out any “cost savings” from

litigating through a class. *Sanneman v. Chrysler Corp.*, 191 F.R.D. 441, 454-55 (E.D. Pa. 2000).

Plaintiffs haven't met either burden. They assert that the class has 65 members and litigating separately would "congest[] the courts." Br. 20-21, 40. But these arguments overstate the size of the class and ignore the case-specific facts that make joinder practicable and preferable.

For one, it is wrong to think about the proposed class as one group of 65 members. There are two theories of liability corresponding to different sets of purchasers: the 32 brand purchasers pursuing a switching theory, and a larger group of 60 generic buyers, which includes 33 generic-only purchasers. Each theory requires a distinct set of proof. For the switching theory, Plaintiffs need to show that brand purchasers would have switched to lamotrigine if Teva had launched earlier. For the generic-purchaser theory, they need to prove that lamotrigine prices would have been lower in with an authorized generic. Jamming the theories together allows Plaintiffs to inflate damages and muddles the proof they will have to put on at trial. The theories should be kept separate, and Plaintiffs must prove that each group of purchasers meets the numerosity requirement on its own. *See Marcus*, 687 F.3d at 595 (rejecting proposed subclass on numerosity grounds). They cannot do so, particularly for the brand-purchaser group, which consists of at most 32 members and drops to 27 if brand-only purchasers are excluded. *See King Drug Co. v. Cephalon, Inc.*, 2017 WL 3705715 (E.D. Pa. Aug. 28, 2017) (rejecting 25-member class); *In re Androgel Antitrust Litig.*, 2018 WL 3424612 (N.D. Ga. July 16, 2018) (rejecting 33-member class).

Even taking both brand and generic purchasers combined, the proposed class still should not be certified. On the numbers, the class is actually smaller than 65 companies due to mergers among members. The size of a class can act as a proxy for "the difficulties of . . . joinder." *Modafinil*, 937 F.3d at 249. But counting heads does not work when companies merge. Legally, the cause of action "passes to the corporation surviving the merger." *Lewis v. Anderson*, 477 A.2d

1040, 1043 (Del. 1984). And practically, the merged entities have a “unity of interests” because their decisions are “under the control of a single driver.” *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 771 (1984). Because merged companies do not litigate separately, they should not count separately for numerosity. Here, that cuts down the class size. Twenty-one of the proposed members have merged with other members, leading to nine combined entities. Hughes ¶¶72-73. That leaves 53 class members, or 48 excluding brand purchasers that did not switch to a generic.

Litigating this case through joinder would be manageable. Even when a class has over 40 members, courts must “ensure that joinder is impracticable” based on “the context of the particular case.” *Modafinil*, 837 F.3d at 249-50. Here, joinder with 53 plaintiffs would not be unwieldy; a larger number of plaintiffs often *opt out* of antitrust class actions. *See, e.g., In re Linerboard Antitrust Litig.*, 223 F.R.D. 357, 360 (E.D. Pa. 2004) (140 opt outs). Nor would litigating through joinder significantly increase the workload for the court or the parties. Plaintiffs need only one set of documents on most issues, including the effects of the settlement and whether an alternative settlement was possible. The named Plaintiffs have also “jointly retained experts” and “join[ed] in motions or responses to motions filed by [GSK].” *King Drug*, 2017 WL 3705715, at *8. There is no reason to think “continuing to do so would not be feasible” if others litigated through joinder. *Id.* Cooperation “has been the norm in . . . related cases,” *id.*, and [REDACTED]

Plaintiffs also have the incentive and ability to litigate through joinder. This is not a class of individuals with “negative value claim[s].” *Modafinil*, 837 F.3d at 257. Rather, it is a group of sizable companies seeking substantial recoveries. Hughes ¶81.⁹ As in *Modafinil*, [REDACTED] putative

⁹ *See In re Park Cent. Glob. Litig.*, 2014 WL 4261950, at *5 (N.D. Tex. Aug. 25, 2014) (rejecting class with over 100 members of “sophisticated investors of substantial means”); *Abu Dhabi Commercial Bank v. Morgan Stanley & Co.*, 269 F.R.D. 252, 257-58 (S.D.N.Y. 2010) (same).

class members “account for [REDACTED] percent of” all brand-generic damages. [REDACTED] *Modafinil*, 837 F.3d at 258. And “the remaining class members” do not have “very small claims.” *Id.* At least [REDACTED] have claims worth [REDACTED] Hughes ¶¶78-79, which the Third Circuit relied on as threshold for when “bringing one’s own suit becomes economical.” *Modafinil*, 837 F.3d at 258-59. Even more stand to win more than one of the named Plaintiffs. Hughes ¶80. Plaintiffs have not shown it “would be uneconomical” for other class members “to be individually joined,” *Modafinil*, 837 F.3d at 259, particularly in light of the reality that “those with . . . small claims[] would likely be represented on a contingent basis,” *King Drug*, 2017 WL 3705715, at *10.¹⁰

Finally, Plaintiffs cannot justify this Rule 23(b)(3) class action because the numerous individualized issues make it no better than litigating through joinder. To avoid a Rules Enabling Act and *Comcast* problem, Plaintiffs would need to create a new method of calculating brand-generic damages that is specific to brand purchasers. *Supra* II.A. To prove brand injury, they would need separate trials on causation for purchasers that did not buy brand during Teva’s exclusivity. *Supra* II.B. And to prove generic-only injury, they would need mini-trials comparing actual and hypothetical generic prices. *Supra* III. Breaking off the “core liability trial” from these “mini-trials on causation” and damages would “defeat the purported economies of class treatment.” *Sanneman*, 191 F.R.D. at 455. None of these complex issues were involved in the other reverse-payment cases Plaintiffs cite, since those class actions did not try to lump brand and generic-only purchasers together. That difference is decisive.

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs’ motion.

¹⁰ This analysis also applies to any class limited to the 60 generic purchasers. That group has 56 members after mergers, the [REDACTED] could win [REDACTED] Hughes ¶78, Exs. 2, 15.

Dated August 8, 2018
Respectfully submitted,

/s/ Michael Patunas
Michael E. Patunas
PATUNAS LAW LLC
24 Commerce Street, Suite 606
Newark, NJ 07102
(973) 396-8740

Jay P. Lefkowitz, P.C.
Devora W. Allon
Dmitriy Tishyevich
Thomas S. Burnett
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
(212) 446-4800

Attorneys for Teva Industries Ltd. and Teva Pharmaceuticals USA, Inc.

/s/ Gavin Rooney
Gavin Rooney
Joseph Fischetti
LOWENSTEIN SANDLER LLP
One Lowenstein Drive
Roseland, NJ 07068
(973) 597-2500

Robin Sumner
Daniel Boland
Lindsay Breedlove
PEPPER HAMILTON LLP
3000 Two Logan Square
Eighteenth & Arch Streets
Philadelphia, PA 19103-2799
(215) 981-4000

Attorneys for GlaxoSmithKline LLC